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on May 3, 2006

Glenn P. Ladwig
Glenn P. Ladwig, Patent Attorney

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

Examining Group 1632
Patent Application
Docket No. USF-182XC1
Serial No. 10/655,873

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Louis D. Lieto, Ph.D.
Art Unit : 1632
Applicants : Shyam S. Mohapatra, Mukesh Kumar
Serial No. : 10/655,873
Filed : September 5, 2003
For : Genetic Adjuvants for Immunotherapy

MS AMENDMENT
Commissioner for Patents
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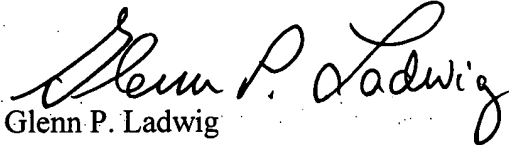
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§1.97 AND 1.98

Sir:

In accordance with 37 C.F.R. §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed. However, the applicants have not submitted copies of the U.S. patents or published U.S. applications cited on attached Form PTO/SB/08 pursuant to 37 C.F.R. §1.98(a)(2)(ii).

The applicants respectfully assert that the substantive provisions of 37 C.F.R. §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,



Glenn P. Ladwig

Patent Attorney

Registration No. 46,853

Phone No.: 352-375-8100

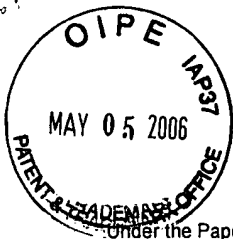
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Attachments: Form PTO/SB/08 (7 pages); copies of some references cited therein



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/655,873
				Filing Date	September 5, 2003
				First Named Inventor	Shyam S. Mohapatra
				Art Unit	1632
				Examiner Name	Louis D. Lieto, Ph.D.
Sheet	1	of	7	Attorney Docket Number	USF-182XC1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-10/526,584	03-03-2005	Mohapatra (patent application)	All
	U2	US-10/544,145	08-02-2005	Mohapatra (patent application)	All
	U3	US-2003/0068333 A1	04-10-2003	Mohapatra et al.	All
	U4	US-2004/0009152 A1	01-15-2004	Mohapatra et al.	All
	U5	US-2005/0025742 A1	02-03-2005	Engler et al.	All
	U6	US-2005/0054052 A1	03-10-2005	Carr et al.	All
	U7	US-2005/0054053 A1	03-10-2005	Aguinaldo et al.	All
	U8	US-2005/0084478 A1	04-21-2005	Liu et al.	All
	U9	US-2005/0266093 A1	12-01-2005	Mohapatra	All

FOREIGN PATENT DOCUMENTS						
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	F1	WO 01/22970 A1	04-05-2001	Cleveland Clinic Found.	All	
	F2	WO 03/028759 A1	04-10-2003	Univ. South Florida et al.	All	
	F3	WO 03/092618 A2	11-13-2003	Univ. South Florida	All	
	F4	WO 04/074314 A2	09-02-2004	Univ. South Florida	All	
	F5	WO 2004/022003 A2	03-18-2004	Univ. South Florida	All	
	F6	WO 2005/094420 A2	10-13-2005	Univ. South Florida	All	
	F7	WO 90/09780 A1	09-07-1990	Danbiosyst UK Lmted.	All	
	F8	WO 98/02457 A1	01-22-1998	Connaught Lab. Lmted.	All	

Examiner Signature		Date Considered	
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	U10	US-2005/0272650 A1	12-08-2005	Mohapatra	All
	U11	US-4,414,150	11-08-1983	Goeddel	All
	U12	US-4,456,748	06-26-1984	Goeddel	All
	U13	US-4,678,751	07-07-1987	Goeddel	All
	U14	US-4,695,623	09-22-1987	Stabinsky	All
	U15	US-4,897,471	01-30-1990	Stabinsky	All
	U16	US-5,770,191	06-23-1998	Johnson et al.	All
	U17	US-5,831,062	11-03-1998	Taylor	All
	U18	US-5,853,755	12-29-1998	Foldvari	All

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				First Named Inventor	Shyam S. Mohapatra
				Art Unit	1632
				Examiner Name	Louis D. Lieto, Ph.D.
Sheet	3	of	7	Attorney Docket Number	USF-182XC1

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	U19	US-6,120,762	09-19-2000	Johnson et al.	All
	U20	US-6,218,180 B1	04-17-2001	Kurtzman et al.	All
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			Group Art Unit	1632	
			Examiner Name	Louis D. Lieto, Ph.D.	
			Attorney Docket Number	USF-182XC1	
Sheet	4	of	7		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	R1	ANTONIOU, K.M. <i>et al.</i> "Interferons and their application in the diseases of the lung" <i>Chest</i> , 2003, 123:209-216.		
	R2	BEHERA, A.K. <i>et al.</i> "2'-5' oligoadenylate synthetase plays a critical role in interferon- γ inhibition of respiratory syncytial virus infection of human epithelial cells" <i>J. Biol. Chem.</i> , 2002, 277(28):25601-25608.		
	R3	CEVC, G. <i>et al.</i> "Ultraflexible vesicles, transfersomes, have an extremely low pore penetration resistance and transport therapeutic amounts of insulin across the intact mammalian skin" <i>Biochim. Biophys. Acta</i> , 1998, 1368:201-215.		
	R4	COLLINS, P.L. <i>et al.</i> "Production of infectious human respiratory syncytial virus from cloned cDNA confirms an essential role for the transcription elongation factor from the 5' proximal open reading frame of the M2 mRNA in gene expression and provides a capability for vaccine development" <i>PNAS USA</i> , 1995, 92:11563-11567.		
	R5	CONNORS, M. <i>et al.</i> "Respiratory syncytial virus (RSV) F, G, M2 (22K), and N proteins each induce resistance to RSV challenge, but resistance induced by M2 and N proteins is relatively short-lived" <i>J. Virology</i> , 1991, 65:1634-1637.		
	R6	DOMACHOWSKIE, J. and ROSENBERG, H. "Respiratory syncytial virus infection: Immune response, immunopathogenesis, and treatment" <i>Clin. Microbiol. Rev.</i> , 1999, 12:298-309.		
	R7	DOW, S. <i>et al.</i> "Systemic and local interferon γ gene delivery to the lungs for treatment of allergen-induced airway hyperresponsiveness in mice" <i>Human Gene Therapy</i> , 1999, 10:1905-1914.		
	R8	FOLDVARI, M. and MORELAND, A. "Clinical observations with topical liposome-encapsulated interferon alpha for the treatment of genital papillomavirus infections" <i>J. Liposome Res.</i> , 1997, 7:115-126.		
	R9	FOLDVARI, M. <i>et al.</i> "Liposome encapsulated prostaglandin E ₁ in erectile dysfunction: Correlation between in vitro delivery through foreskin and efficacy in patients" <i>Urology</i> , 1998, 52(5):838-843.		
	R10	GOEDDEL, D. <i>et al.</i> "The structure of eight distinct cloned human leukocyte interferon cDNAs" <i>Nature</i> , 1981, 290:20-26.		
	R11	GUTTERMAN, J.U. "Cytokine therapeutics: Lessons from interferon α " <i>Proc. Natl. Acad. Sci. USA</i> , 1994, 91:1198-1205.		
	R12	HELLERMANN, G.R. and MOHAPATRA, S.S. "Genetic therapy: on the brink of a new future" <i>Gen Vacc & Ther.</i> , 2003, 1:1.		
	R13	HENCO, K. <i>et al.</i> "Structural relationship of human interferon alpha genes and pseudogenes" <i>J. Mol. Biol.</i> , 1985, 185:227-260.		

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				Group Art Unit	1632
				Examiner Name	Louis D. Lieto, Ph.D.
				Attorney Docket Number	USF-182XC1
Sheet	5	of	7		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R14	HOFSTRA, C. <i>et al.</i> "Differential effects of endogenous and exogenous interferon- γ on immunoglobulin E, cellular infiltration, and airway responsiveness in a murine model of allergic asthma" <i>Am. J. Respir. Cell Mol. Biol.</i> , 1998, 19:826-835.	
	R15	HSU, S-C. <i>et al.</i> "Synergistic effect of immunization with a peptide cocktail inducing antibody, helper and cytotoxic T-cell responses on protection against respiratory syncytial virus" <i>J. Gen. Virology</i> , 1999, 80:1401-1405.	
	R16	HUANG, T-J. <i>et al.</i> "Allergen-specific Th1 cells counteract efferent Th2 cell-dependent bronchial hyperresponsiveness and eosinophilic inflammation partly via IFN- γ " <i>J. Immunol.</i> , 2001, 166:207-217.	
	R17	JAMETON, R. and MOHAPATRA, S.S. "IL-12 possibilities" <i>Science</i> , 1995, 269(5230):1498-1499.	
	R18	KUMAR, M. <i>et al.</i> "Role of mucosal IFN- γ gene transfer on allergic sensitization and RSV infection" <i>J. Allergy Clin. Immunol.</i> , 2002, 109:S4, abstract no. 78.	
	R19	KUMAR, M. <i>et al.</i> "Intranasal gene transfer by chitosan-DNA nanospheres protects BALB/c mice against acute respiratory syncytial virus infection" <i>Hum. Gene Ther.</i> , 2002, 13(12):1415-1425.	
	R20	LENGYEL, P. "Tumor-suppressor genes: News about the interferon connection" <i>Proc. Natl. Acad. Sci. USA</i> , 1993, 90:5893-5895.	
	R21	LEONG, K.W. <i>et al.</i> "DNA-polycation nanospheres as non-viral gene delivery vehicles" <i>J. Controlled Release</i> , 1998, 53:183-193.	
	R22	LI, X. <i>et al.</i> "Protection against respiratory syncytial virus infection by DNA immunization" <i>J. Exp. Med.</i> , 1998, 188:681-688.	
	R23	LI, X. <i>et al.</i> "Plasmid DNA encoding the respiratory syncytial virus G protein is a promising vaccine candidate" <i>Virology</i> , 2000, 269:54-65.	
	R24	MAO, H-Q. <i>et al.</i> "Chitosan-DNA nanoparticles as gene carriers: synthesis, characterization and transfection efficiency" <i>J. Controlled Release</i> , 2001, 70(3):399-421.	
	R25	MOHAPATRA, S.S. "Mucosal gene expression vaccine: a novel vaccine strategy for respiratory syncytial virus" <i>Pediatr. Infect. Dis. J.</i> , 2003, 22(2 Suppl):S100-S104.	
	R26	MONTGOMERY, D. <i>et al.</i> "DNA vaccines" <i>Pharmacol. Ther.</i> , 1997, 74:195-205.	

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	R27	MURRAY, H.W. "Current and future clinical applications of interferon-gamma in host antimicrobial defense" <i>Intensive Care Med</i> , 1996, 22(Suppl 4):S456-S461.	
	R28	OKUBO, T. <i>et al.</i> "Administration of an IL-12-encoding DNA plasmid prevents the development of chronic graft-versus-host disease (GVHD)" <i>J Immunol</i> , 1999, 162:4013-4017.	
	R29	OPDENAKKER, G. <i>et al.</i> "Interaction of interferon with other cytokines" <i>Experientia</i> , 1989, 45:513-520.	
	R30	PARK, S-Y. <i>et al.</i> "IFN- γ enhances TRAIL-induced apoptosis through IRF-1" <i>Eur. J. Biochem.</i> , 2004, 271(21):4222-4228.	
	R31	PIZZOFERRATO, F. <i>et al.</i> "Ectopic expression of interferon regulatory factor-1 promotes human breast cancer cell death and results in reduced expression of survivin" <i>Cancer Res.</i> , 2004, 64(22):8381-8388.	
	R32	RENER, X. <i>et al.</i> "Construction and identification of a recombinant adenovirus which expresses human interferon- γ " <i>Chinese J. Biotech.</i> , 1997, 13:1-8.	
	R33	ROBINSON, M. and KAWABATA, T. "Predictive assessment of respiratory sensitizing potential of proteins in mice" in <i>Toxicology of Chemical Respiratory Hypersensitivity</i> , Dearman and Kimber, Eds., 1997, pp. 135-150.	
	R34	ROY, K. <i>et al.</i> "Oral gene delivery with chitosan-DNA nanoparticles generates immunologic protection in a murine model of peanut allergy" <i>Nat Med</i> , 1999, 5:387-391.	
	R35	SETHI, S.K. <i>et al.</i> "Interferon-gamma (IFN- γ) down-regulates the rhinovirus-induced expression of intercellular adhesion molecule-1 (ICAM-1) on human airway epithelial cells" <i>Clin. Exp. Immunol.</i> , 1997, 110:362-369.	
	R36	SHORT, S.M. <i>et al.</i> "Percutaneous absorption of biologically-active interferon-gamma in a human skin graft-nude mouse model" <i>Pharm. Res.</i> , 1996, 13:1020-1027.	
	R37	SIMMONS, C.P. <i>et al.</i> "Mucosal delivery of a respiratory syncytial virus CTL peptide with enterotoxin-based adjuvants elicits protective, immunopathogenic, and immunoregulatory antiviral CD8 ⁺ T cell responses" <i>J. Immun.</i> , 2001, 166:1106-1113.	
	R38	STREULI, M. <i>et al.</i> "At least three human type α interferons: Structure of $\alpha 2$ " <i>Science</i> , 1980, 209:1343-1347.	
	R39	TANG, Y-W. <i>et al.</i> "Determinants and kinetics of cytokine expression patterns in lungs of vaccinated mice challenged with respiratory syncytial virus" <i>Vaccine</i> , 1997, 15:597-602.	

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/655,873	
			Filing Date	September 5, 2003	
			First Named Inventor	Shyam S. Mohapatra	
			Group Art Unit	1632	
			Examiner Name	Louis D. Lieto, Ph.D.	
			Attorney Docket Number	USF-182XC1	
Sheet	7	of	7		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R40	WRIGHT, P. <i>et al.</i> "Evaluation of a live, cold-passaged, temperature-sensitive, respiratory syncytial virus vaccine candidate in infancy" <i>J. Infect. Dis.</i> , 2000, 182:1331-1342.	
	R41	WYATT, L.S. <i>et al.</i> "Priming and boosting immunity to respiratory syncytial virus by recombinant replication-defective vaccinia virus MVA" <i>Vaccine</i> , 2000, 18:392-397.	
	R42	YOSHIDA, M. <i>et al.</i> "Effect of interferon-γ on allergic airway responses in interferon-γ-deficient mice" <i>Am J Respir Crit Care Med</i> , 2002, 166:451-456.	
	R43	ZOON, K.C. "Human interferons: Structure and function" <i>Interferon</i> , 1987, 9:1-12.	
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Examiner Signature		Date Considered	
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